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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,316	01/18/2002	Chakradhara S. Rao	J&J-2087	2986

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EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,316	RAO ET AL.	
	Examin r	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election acknowledged

Applicants affirmation on the election with traverse of Group I, claims 1-10 is acknowledged. Applicant requested a traverse the restriction requirement on the grounds that there would be no burden in searching the entire application. This argument is not persuasive, as not all groups encompassed by the application would be classified together. As mentioned in previous office action, each invention is found to be patentably distinct subject matter proven in numerous patent literatures. For example. Wilmott et al (US 4,826,828) or Liu(US 6,193,956) teaches a topical retinoid composition in two-part container formulated to improve the stability of retinoid compounds. However, these references appear to demonstrate that each of the inventions does not define a contribution, considered as a whole, makes over the prior art. Furthermore even if there were unity of classification, the search of the entire application in patent and non-patent literature (a significant part of the thorough examination) would be burdensome due to the reasons mentioned in previous office action(e.g. patentably distinct subject matter proven in numerous patent literature). Therefore the restriction requirement is maintained and made FINAL.

Status of Application

1. Claims 1-20 are pending. The elected claims 1-10 are presented for the examination and the claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claims, there being no allowable

generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al(US 6,200,597).

US'597 teaches a formulation and use of carotenoids wherein the carotenoids are referring to retinoids, pro-retinoids, phenyl analog of retinoic acid and analogs thereof, see abstract and column 2, lines 60-65 and column 6, lines 15-24. It further teaches a method of administering said carotinoids composition by topical application via reconstitution method. Especially at column 20, lines 55-68 and column 7, lines 38, in vivo administration, the solid powder mixture of liposomes and liposomal all-trans retinoid acid is reconstituted by adding 3ml of normal saline to each bottle and agitating the suspension, immediately before use. At column 7, lines 15-25, t-butanol is also taught as a solvent to dissolve the active agent. US'597 further teaches triglycerides as preferred additives to enhance the quality of the composition, see column 7, lines 7-12.

Applicants claims differ in that they require a retinoid derivative having specific formula I as shown in the instant claim 1.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Mehta's teaching to include the compounds of formula I as taught in Klaus reference because Klaus et al(US'956) teaches the compounds of formula I as selective ligands of retinoic acid receptors, see abstract. It also teaches that the topical formulations of said active substances can be prepared by non-toxic, inert solid or liquid carriers(triglycerides, ethanol, etc) wherein topical preparation containing the compounds of formula I shows superior therapeutic activity compared to trans- or cis-retinoic acids, see column 4, lines 8-15 and 55-60. As to the claims 6 and 8, the minor variations including the selection of suitable carriers(i.e. gelling agent recited in claim 6), optimal dosages and storage environment(i.e. refrigeration), routes of administration, or variable applications in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious, absent evidence to the contrary.

One would have been motivated to make such modification, with reasonable expectation of success, because the stability is most critical and essential elements in manufacturing pharmaceutical product where the said modification improves not only therapeutic activities but also stability and efficacy of the treatment. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a). Since each patentee teaches the compounds having activities to retinoic acid receptors indicating that they have same pharmacore(structure that

activates the receptor and responsible for the therapeutic effect) and each patentee also teaches topical formulations using conventionally known carriers.

Conclusion

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
April 30, 2003
Art unit 1614